



AND



Integrated Drug Development News

Fall 2006

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Cato Research Staff Thanked for Regulatory Support—*Regulatory expertise key to approval of BabyBig®*

Dr. Allen Cato and Lynda Sutton, cofounders of Cato Research, and other Cato Research regulatory experts, received recognition for their regulatory expertise in the February 2006 issue of the New England Journal of Medicine (NEJM). Cato Research provided crucial regulatory support to the California Department of Health Services' (CDHS) development of Human Botulism Immune Globulin Intravenous (BIG-IV) for the treatment of infant botulism.

Due to Cato Research's regulatory assistance, BIG-IV, known as BabyBIG®, was approved by the United States Food and Drug Administration to treat the orphan indication infant botulism type A and type B. BabyBIG® was shown in clinical studies to shorten the duration of intensive care treatment, the overall

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Cato Research and JSW-Research Sign Strategic Collaboration



Agreement—*CATO expands into two more European markets; strengthens CNS drug development capabilities*

Cato Research Ltd., a global contract research organization (CRO) providing comprehensive drug development services and regulatory expertise for clients in the pharmaceutical, biotechnology, and medical device industries, and Austrian CRO JSW-Research Forschungslabor GmbH, specializing in research and development of novel therapeutics for central nervous system (CNS) disorders, announced a strategic business development collaboration focused

"Our collaboration with JSW is another critical component in our global strategic plan...to offer a comprehensive portfolio of essential CRO services to our sponsors worldwide."

Allen Cato, M.D., Ph.D., cofounder and CEO of Cato Research

on expansion of the Companies' operations throughout the European Union and Eastern Europe. The new strategic arrangement follows a successful long-term relationship between Cato and JSW involving numerous large-scale clinical trial programs in the European Union. "By partnering with JSW-Research, we have now extended our reach into two more important markets and strengthened our capabilities in the ever-growing CNS drug development arena", said Allen Cato, M.D., Ph.D., cofounder and Chief Executive Officer of Cato Research. □

CALENDAR OF UPCOMING REGIONAL AND NATIONAL EVENTS

OCTOBER 2006

MASSACHUSETTS BIOTECH COUNCIL ANNUAL CAREER FAIR
18 OCTOBER 2006
SHERATON BOSTON HOTEL, BOSTON, MA

2006 LIFE SCIENCES VENTURE SUMMIT
25 OCTOBER 2006
HOTEL PENNSYLVANIA, NEW YORK, NY

NOVEMBER 2006

2006 MASS OPPORTUNITIES: A BIOTECHNOLOGY
INVESTMENT CONFERENCE
02 NOVEMBER 2006
LOGAN AIRPORT HILTON, BOSTON, MA

NECACRP SYMPOSIA (SPONSORED BY CATO RESEARCH)
03 NOVEMBER 2006
WESTIN HOTEL, WALTHAM, MA

DRUG DEVELOPMENT IN INDIA
16-17 NOVEMBER 2006
BOSTON PARK PLAZA, BOSTON, MA

NANOBIOTECH WORLD CONGRESS
16-17 NOVEMBER 2006
RADISSON HOTEL, BOSTON MA

7TH ANNUAL FORUM ON BIOTECH PATENTS
29- 30 NOVEMBER 2006
LANGHAM HOTEL, BOSTON MA

DECEMBER 2006

2ND MODERN DRUG DISCOVERY AND DEVELOPMENT SUMMIT
04-06 DECEMBER 2006
PHILADELPHIA CONVENTION CENTER, PHILADELPHIA, PA

2007

BIO-IT WORLD CONFERENCE & EXPO
APRIL 30 – MAY 2, 2007
WORLD TRADE CENTER, BOSTON, MA.

BIO INTERNATIONAL CONVENTION
MAY 6-9, 2007
BOSTON CONVENTION AND EXHIBITION CENTER, BOSTON, MA

*FOR A COMPREHENSIVE LISTING OF DRUG DEVELOPMENT AND
BIOTECHNOLOGY EVENTS WORLDWIDE, PLEASE VISIT THE CATO
BIOTECHNOLOGY CALENDAR: [HTTP://WWW.CATO.COM/FYI/](http://www.cato.com/fyi/)*

New Safety Software Implemented at Cato

Research—*Argus Safety provides capability for electronic safety*

The Pharmacovigilance group at Cato Research is excited to announce the implementation of new safety software, Argus Safety (Relsys International). Argus Safety provides the capability for electronic submissions of safety reports to the EMEA. Also, the system features advanced searching and reporting functionality, a web-based platform, and E2b format for exchange with other safety databases or EDC systems. The “Go Live” date for phase I of Argus Safety was 31 March 2006 and phase II (electronic submissions) is October 2006. For more information on the CATO Pharmacovigilance services and Argus Safety please contact Laurie Girard, Associate Director of Pharmacovigilance, by email at lgirard@cato.com or by phone at 919-361-2286. □

VistaGen Therapeutics and Cato BioVentures Sign Strategic Business Development Agreement for CNS Products

VistaGen Therapeutics Inc., a biopharmaceutical company applying leading embryonic stem cell technology to discover and develop novel treatments for central nervous system disorders, diabetes and cardiovascular disease, and Cato BioVentures, the venture capital affiliate of Cato Research, announced today the signing of a strategic business development agreement. The agreement grants VistaGen exclusive rights of first negotiation to all CNS product opportunities identified or acquired by Cato BioVentures and Cato Research. H. Ralph Snodgrass, Ph.D., VistaGen’s President and CEO, noted, “This CNS product option arrangement allows us to expand our strategic relationship with Cato and access its broad range of business development capabilities in our core therapeutic focus area. Our operating capital requirements remain low, which reduces risk, yet we now have the important product

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Regulatory Support, continued from page 1

duration of hospitalization, and the cost of treatment. This was the first orphan product developed and licensed by a state department of health. Dr. Stephen Arnon, Chief of the California Infant Botulism Treatment and Prevention Program, is quoted, "In achieving licensure for BabyBIG[®], Cato Research has provided CDHS with outstanding quality, technical capability, and performance."

Infant botulism affects infants up to one year of age as a result of ingesting *Clostridium botulinum* spores. It can cause loss of muscle tone, as well as create difficulty for feeding and breathing. For more information on infant botulism, visit www.infantbotulism.com. To access the NEJM article, *Human Botulism Immune Globulin for the Treatment of Infant Botulism*, please visit: <http://content.nejm.org/cgi/content/abstract/354/5/462> □

VistaGen Strategic Business Agreement, continued from page 2

acquisition upside potential of a fully integrated drug development company." Shawn K. Singh, J.D., Managing Principal of Cato BioVentures, and a member of VistaGen's Board of Directors added, "VistaGen's CNS focus and leading embryonic stem cell-based drug discovery and development technology provide an ideal leverage opportunity for our expanding CNS product acquisition and investment activities. Allen Cato, M.D., Ph.D., co-founder and Chief Executive Officer of Cato Research explained, "We have access to dozens of CNS product acquisition and development opportunities each year through our long standing relationships with biotechnology and pharmaceutical companies and academic institutions worldwide. Under our new agreement, these CNS product opportunities are now available to VistaGen. We have built a strong strategic drug development relationship with VistaGen around its lead CNS product candidate, AV-101, a promising new compound focused on epilepsy and neuropathic pain." We look forward to expanding that relationship with additional CNS product candidates." □

ABOUT CATO RESEARCH

Founded in 1988 by Dr. Allen Cato and Lynda Sutton and headquartered near Research Triangle Park, NC, Cato Research is a full-service contract research organization providing strategic and tactical support for clients in the pharmaceutical, biotechnology, and medical device industries. Services range from design and management of preclinical and clinical studies to submission of the regulatory documents required for marketing approval. With a staff of over 300 located in the United States, Canada, Germany, Austria, Latvia, Israel, and South Africa, the Cato Research team consistently demonstrates an unsurpassed level of responsiveness, flexibility, attention to detail, and passion in bringing a sponsor's products to market rapidly and cost effectively. For more information, visit the company's web site at www.cato.com or call Cato Research in Durham, NC at 919-361-2286 to speak directly with one of our drug development experts.

ABOUT CATO BIOVENTURES

Cato BioVentures is the venture capital affiliate of Cato Research Ltd. For nearly 20 years, Cato BioVentures has assisted both entrepreneurs and established management teams to build successful life science companies. Through strategic CRO service agreements with Cato Research, Cato BioVentures invests its in-kind CRO Service Capital™ in innovative therapeutics, medical devices, diagnostics, and platform tools and technologies for improved drug discovery and development. Cato BioVentures offers promising life science companies immediate access to a broad range of essential CRO services on a noncash basis. Access to these time-critical CRO services enables management to achieve key value-added development and regulatory milestones with less reliance on other sources of capital. Cato BioVentures has offices in Boston's Bay Colony, Research Triangle Park (Durham, NC), and in Northern and Southern California. For more information, visit the Cato BioVentures web site at www.catobioventures.com.



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Graz, Austria

STUDIKA-CATO RESEARCH:

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Riga, Latvia

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A full-service, international contract research and development organization, helping sponsors achieve success in creating better health for people everywhere.



Assisting entrepreneurs and established management teams build successful life science companies.

Strategies. Solutions. Success. Making a difference in drug development.